

REMARKS

Claims 1-20 and 102 are pending. Claims 1, 2, 6, 8, 19, and 102 are amended herein and claims 5 and 7 are canceled herein, all without prejudice and without acquiescence. Support for amendments to the claims is found at least in the original claims and in paragraph [0070]. Applicants reserve the right to pursue amended and canceled material in subsequent prosecution. No new matter is entered herein.

I. Issue of the Information Disclosure Statement

The Examiner noted that the listing of references on PTO 1449 was incomplete and particularly notes citations CB, CC, and CD. Applicants regret and herewith submit a Supplemental IDS to correct the inadvertent typographical error. Applicants have been unable to identify a date for reference CA but continue to seek this information.

II. Interview Summary

On November 17, 2006, the undersigned had a telephonic interview with the Examiner. Participants discussed the outstanding issues under 35 USC §112, first and second paragraphs, and no prior art was discussed. Applicants thank the Examiner for the courtesy of the teleconference.

III. Issues under 35 USC §112, first paragraph

Claims 6-8 were rejected under 35 USC §112, first paragraph as allegedly failing to comply with the enablement requirement for claimed subject matter that was not described in the specification in such a way as to enable one of skill in the art to make and use the invention. Applicants respectfully disagree.

In particular, page 3 of the Action states that these claims concern adding water or a hypotonic solution to the physiological solution (whole blood or bone marrow aspirate, for example) and, if a sufficient amount is added, this can result in lysis of a cell. The Action then makes the unfounded supposition that it is not possible to collect a retentate comprising cells when the starting physiological solution has water or a hypotonic solution added that would allegedly necessarily result in lysis.

Applicants disagree that the claims are not enabled, because Applicants show the skilled artisan how to make and use the invention. In particular, Applicants provide at least

one exemplary embodiment of a sufficient ratio of water to blood in paragraph [0190] of the specification, Example 8, for example, which describes the use of 10 ml water for injection in combination with 60 ml of anti-coagulated blood. The exemplary amount of water or hypotonic solution that is added to the cell suspension in the invention is *insufficient* to cause significant cell lysis, as exemplified by the platelet counts (see at least paragraph [0193] and FIG. 13). Furthermore, it is well known in the art that adding sufficient water or sufficient hypotonic solution to a cell suspension will result in cell lysis, so one of skill in the art would be able to empirically determine the appropriate amounts without undue experimentation. As an example, Applicants submit in a Supplemental IDS herewith an excerpt from Wintrobe's Clinical Hematology, Tenth Edition (eds. Lee *et al.*) that demonstrates that one of skill in the art was aware not only that cell lysis could generally occur but how to test for cell lysis based on the exemplary osmotic fragility test (see at least p. 1124-1125, FIG. 40.10, and Table A.12). Therefore, one of skill in the art would have been aware not only that the amount of hypotonic solution added to the physiological fluid should be carefully considered but how to test which amounts of hypotonic solution were suitable.

Applicants respectfully request withdrawal of the rejection.

IV. Issues under 35 USC §112, second paragraph

A. Claims 1-20 and 102

Claims 1-20 and 102 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants respectfully disagree.

In particular, the Action states that bone marrow aspirate or blood are not solutions because they are not a homogeneous mixture. Although Applicants do not necessarily acquiesce that this definition is pertinent to all possible embodiments of the term, solely to further the prosecution of this case Applicants amend the appropriate claims herein. Applicants respectfully request withdrawal of the rejection.

B. Claim 19

Claim 19 is rejected for lacking antecedent basis for the term "the second product." Applicants amend claim 19 herein to correct this inadvertent typographical error.

C. Clarification of the Claimed Method

Under the 35 USC §112, second paragraph section of the Action, on page 3, the Examiner acknowledges difficulty in understanding how a leukoreduction filter that retains cells of about 10 microns (for example, leukocytes) can also retain small platelets without agglomeration of the platelets. The Examiner requests clarification of the claimed method.

Applicants acknowledge that the exemplary leukoreduction filters in the invention have been generally employed specifically to entrap leukocytes based on their cell size, typically in the tens of microns. In the invention, therefore, it is surprising and unexpected that such a filter can be used to separate platelets (typical size of 1.5 microns) from other fluid components. This factor illustrates the non-obviousness of the invention.

V. Issues under 35 USC §102**A. WO 02/089737**

Claims 1-6 and 9-20 were rejected under 35 USC §102(e) as allegedly being anticipated by WO 02/089737. Applicants respectfully disagree.

The rejected claims recite that the filter retentate from the physiological solution comprises at least nucleated cells greater per unit volume than in the physiological solution **and** that the permeate solution comprises plasma and red blood cells. WO 02/089737 states at least on page 12, lines 8-10 that whole blood components, including leukocytes, pass through the filter. Therefore, at the very least for this reason this reference does not teach all elements of the present invention, and Applicants respectfully request withdrawal of the rejection.

B. U.S. Patent No. 6,544,751

Claims 1-7 and 102 were rejected under 35 USC §102(e) as allegedly being anticipated by U.S. Patent No. 6,544,751.

As submitted herewith, independent claims 1 and 102 recite that a hypotonic fluid is added to the physiological fluid and also that the filter retentate comprises nucleated cells and platelets. U.S. Patent No. 6,544,751 does not teach all elements of these submitted claim amendments, and Applicants respectfully request withdrawal of the rejection.

C. Blazsek *et al.* (1999)

Claims 1-4 and 120 were rejected under 35 USC §102(b) as allegedly being anticipated by Blazsek *et al.* 1999. (“Blazsek”).

Again, as submitted herewith, independent claims 1 and 102 recite that a hypotonic fluid is added to the physiological fluid. At the very least, Blazsek does not teach all elements of the submitted claim amendment, and Applicants respectfully request withdrawal of the rejection.

D. WO 01/72369

Claims 1-5, 20, and 102 were rejected under 35 USC §102(b) as allegedly being anticipated by WO 01/72369.

Independent claims 1 and 102 as amended herein recite that a hypotonic fluid is added to the physiological fluid and also that the filter retentate comprises both nucleated cells and platelets. WO 01/72369 does not teach all elements of these submitted claim amendments, and Applicants respectfully request withdrawal of the rejection.

VI. Issues under 35 USC §103(a)

Claims 1-20 and 102 were rejected under 35 USC §103(a) as allegedly being unpatentable over WO 01/72369 in combination with U.S. Patent No. 7,056,738; U.S. Patent No. 5,824,084; and U.S. 2004/0071668. Applicants respectfully disagree.

The use of filters with a specific pore size to purify materials including cells based on size is well-known. It would therefore be expected that the use of the exemplary leukoreduction filter (as is used in normal operation) would result in leukocytes being retained on the filter medium, while the erythrocytes, platelets and serum would be comprised in the permeate fluid. However, surprisingly the use of a hypotonic saline solution, such as water, for example, allows the unexpected simultaneous filtration of both leukocytes and platelets in a single filtration step.

Even the Examiner on page 3 of the Action acknowledges the unexpected result of the invention that platelets can be isolated by an exemplary leukoreduction filter. It is certainly surprising that one filter can allow concomitant isolation of cells of such varying sizes when it is expected that the smaller-sized platelets should pass through with the permeate solution.

In the invention, the addition of a hypotonic solution does not swell the platelets to such an extent that they would be expected to be retained on a leukoreduction filter: such an osmotic shock would be expected to result in cell lysis, and it would therefore be surprising to be included as an element of experimental design. This further supports patentability of the invention and that the references do not teach or suggest the invention.

Applicants respectfully request withdrawal of the rejection.

VII. Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants believe no fees are due with this response other than the fees for the Supplemental IDS and the Petition for Extension of Time of Three Months. However, if another fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02759US3 from which the undersigned is authorized to draw.

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Respectfully submitted,

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